REMARKS

Claims 1-24 are pending. Applicant notes the withdrawal of the rejection under 35 U.S.C. § 102(b). The remainder of the rejections will be addressed below.

Rejections under 35 U.S.C. § 103

The Examiner noted the arguments submitted by Applicant in the previously submitted Amendment. However, the Examiner has maintained the rejection. Specifically, the Examiner states:

"Applicant's arguments filed February 28, 2008, have been fully considered but they are not persuasive because the arguments are intended use recitations:

In regards to claims 1, 4, 5, 11, 19, 21, 22, and 24, in response to applicant's argument that the device of Inman et al (US 4,578,063) does not disclose a swivel joint that could be combined with the Cuppy (US 5,755,709) patent to obtain the claimed invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant argues that since the device of Inman et al is implanted into the body with the swivel joint [42][sic] implanted into the body, the device will encourage ingrowth of connective tissue and vascularization leading to the eventual inability of the swivel joint to rotate relative to the device (Reply, page 10, paragraph 2). Examiner agrees with this rationale that the connective tissue and the vasculature will grow to surround the device and prevent rotation of the swivel joint; however, Examiner is only using the structural concept of the swivel joint of Inman et al to modify the device of Cuppy so that the subhousing of Cuppy will be able to move within various bends or angles (Inman et al, column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more

comfortable for the patient. Examiner does not intend for the swivel joint to be implanted into the body, as the subhousing of Cuppy, which is being modified by the swivel joint of Inman et al, will remain outside of the body. Connective tissue and vasculature will not grow around the device as the device will remain outside of the body, and only the catheter that is attached to the device is inserted into the body.

Applicant states the intended use of the device of claims 1, 11, 19, and 24, as the device will allow repositioning of the second end of the subhousing relative to the housing (Reply, page 11, paragraph 1). Applicant states that the swivel joint of Inman et al was designed to be implanted under the skin of the patient (Reply, page 11, paragraph 3); however, such is an intended use recitation of the swivel joint of Inman et al. A swivel joint can be positioned inside or outside of the body. Based on its structure alone, if the swivel joint of Inman et al is applied to the subhousing of Cuppy, then the subhousing will be able to move relative to the housing. The prior art structure of the modified device of Cuppy and Inman et al is capable of performing the claimed intended use."

The rejection is respectfully traversed. It is still the position of the Applicant that Inman does not disclose structures that can be combined with Cuppy to arrive at the claimed invention.

Applicant is not attempting to distinguish over the asserted combination of Cuppy and Inman based on an argument that the "intended use" of the claimed invention is different than Cuppy, Inman or a possible combination of these references. Rather, the argument is that Inman *teaches away* from the combination proposed by the Examiner. Specifically, Inman discloses a structure that is used only during implantation of a device to allow for orientation of the device that will be maintained for the remainder of the duration of the use of the apparatus. The presently claimed invention is novel and unobvious over the cited combination for at least the reason that it allows for external

continuous adjustment of a subhousing (which, in turn, allows introduction of fluids into a body) during the entire time the invention is in use.

According to MPEP 707.07(f), Paragraph 7.37.09, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. However, no prior art structure is available to the Examiner that is capable of performing the alleged intended use. In this case, one element of the disclosure of Inman is proposed by the Examiner for combination with an element of another prior art disclosure. The structure alleged to render the presently claimed invention obvious does not exist in the prior art. Therefore, the analysis turns on whether the combination of the disclosure of Inman and the '709 patent is appropriate.

In KSR International Co. v. Teleflex Inc., 127 S.Ct 1727, 82 USPQ2d 1385 (U.S. 2007) the Supreme Court reviewed the standard for making appropriate obviousness rejections. Specifically, the Court reviewed the application of the teaching, suggestion, motivation test that had regularly been applied by the Federal Circuit in order to evaluate the sufficiency of an obviousness rejection. Although the Court rejected the "rigid" application of the test in all circumstances, it did state that test provided useful insights. Specifically, the Court stated:

> "As is clear from cases such as Adams, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

> This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."

The Court also stated that the correct inquiry must ask "...whether the improvement is more than the predictable use of prior art elements according to their established functions."

Thus, the Court still instructs that an obviousness inquiry must look to see what a reference discloses regarding the elements selected by the Examiner for combination with other references, contrary to the Examiner's assertion that a disclosure of "structure alone" is sufficient to construct an obviousness rejection. To state another way, it is not sufficient to cherry pick parts of prior art disclosures and cobble them together in formation of and obviousness rejection. A sound reason underpinning the selection of the alleged elements and for making the combination must be given. The reason for making the combination should also take into account the entire disclosure of the references from which the elements were selected in order to be true to the teachings of the reference and the true state of the prior art.

Clearly, the cited combination of the '709 patent and Inman does not satisfy the classical TSM test to establish a prima facie case of obviousness. The '709 patent discloses a catheter access device. Inman discloses a catheter access device (10) that is inserted surgically connects to an internal body conduit (44) (See e.g. Column 7, Lines 44-45). The connection is made through connector 42 that is secured into the bottom of the device and that is allowed to swivel in some embodiments. Connector 42 is surgically implanted into the patient along with a substantial portion of the device which then becomes *fixed* and non-rotatable. No teaching, suggestion or motivation is provided by the '709 patent or Inman to combine the references in the manner alleged by the Examiner.

Throughout the disclosure of Inman, it is clear that the device (10) is designed to be implanted into the skin of the patient. (See e.g. Claim 1 "A percutaneous implant device...") Logically, connector 42 which connects to an indwelling connector 44 must also be implanted into the patient. Inman's disclosure also makes clear that once the device (10) is implanted (e.g. by a surgeon or medical doctor) into the body of the patient, it desireable that the device adhere to the skin into which it is placed. The device therefore does not move relative to the patient, therefore the device (10) does not swivel relative to connector (42) during the time in which device (10) is in operation.

Importantly, it appears that the Examiner does not apply the disclosure of Inman at column 8, lines 39-42 correctly. This portion of the disclosure is directed toward features of the connector 42 which is interposed between percutaneous device (10) and internal connector 44. Lines 30-36 of Column 8 disclose that connector 42 can swivel, but that the swivel is intended to "...allow proper placement during implantation." Lines 38-39 specify that connector 42 can in fact be securely adhered in place and apparently not allowed to swivel at all. Lines 39-42 specify that the connector 42 can protrude from the device perpendicularly (See e.g. Fig. 4) or can have "various bends and angles depending on the appropriate placement of the internal apparatus." Nothing in the language cited by the Examiner points to construction of a device that can be adjusted relative to the patient while the device is in use. It is clear from this language that the "bends and angles" refers to the static configuration of the connector 42 with respect to the body into which the device 10 is to be implanted. This passage does not provide disclosure for a connector with a dynamic range of motion as alleged in the Final Office Action.

Thus, the Inman reference is not properly combined with the disclosure of the '709 patent under 35 U.S.C. § 103. Reconsideration and withdrawal of the rejection is respectfully requested.

With regard to the remainder of the Final Office Action, specifically paragraphs 6 through 9, it appears that these paragraphs restate the rejections made in the Office Action previously sent to Applicant with the exception of the inclusion of claim 23 in the rejection at paragraph 6 (apparently necessitated by the withdrawal of the rejection of claim 23 under 35 U.S.C. § 102). It does not appear that the Examiner has separately considered the response to these arguments submitted by Applicant and therefore Applicant refers to the Amendment submitted on February 28, 2008 and the responses to the rejections made therein and specifically incorporates by reference all the arguments made in the Amendment submitted on February 28, 2008 into this Response.

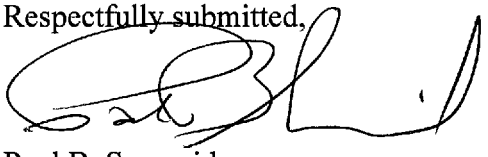
In addition, with respect to claim 19, Applicant notes that the disclosure of Inman clearly teaches away from the claimed method. Claim 19 allows for adjusting the position of the subhousing relative to the housing after the step of connecting the catheter adapter device to a fluid line at the second end of the subhousing. Inman, however, discloses the implantation of a device into the skin, with only a portion protruding. During the implantation, the device may swivel with respect to connector 42. However, the Inman device is specifically designed to encourage ingrowth of surrounding tissue to prevent any further movement or swivel of the device. During the operation of the device of Inman, disturbance of the site of where the device is implanted is to be avoided after installation. (See e.g. Column 2, Lines 33-68) Thus, Inman specifically teaches avoidance of any swivel of the device with respect to connector 42 after implantation of the device. Thus, the disclosure in Inman specifically guides one of ordinary skill in the art away from the combination proposed by the Examiner in rejecting claim 19.

Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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